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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF GEORGIA

MEDLINE INDUSTRIES, INC., an Illinois Corporation,

Plaintiff,

vs.

KIMBERLY-CLARK CORPORATION, a Delaware Corporation; and HALYARD HEALTH, INC., a Delaware Corporation; and DOES 1 through 100, inclusive

Defendants.

CIVIL ACTION NO.: 1:17-CV-2032-SCJ

SECOND AMENDED COMPLAINT FOR:

1. **FALSE ADVERTISING AND PROMOTION IN VIOLATION OF LANHAM ACT SECTION 43(a); AND**
2. **COMMON LAW UNFAIR COMPETITION**

DEMAND FOR JURY TRIAL

SECOND AMENDED COMPLAINT

Plaintiff MEDLINE INDUSTRIES, INC. ("Plaintiff" or "Medline") hereby alleges as follows:

I. BACKGROUND

1. This action seeks redress from defendants Kimberly-Clark Corporation ("Kimberly-Clark") and Halyard Health, Inc. ("Halyard") (collectively, "Defendants") for their false and misleading representations in connection with their advertising, promotion, marketing, and sale of medical gowns, which they claimed provided the highest levels of liquid barrier protection (AAMI Level 3 and 4) from the transfer of bodily fluids, bacteria, and infection between a patient and healthcare professional. Contrary to their representations, Defendants have known since at least as early as 2012 that their MICROCOOL* Breathable High Performance Surgical Gowns (the "MicroCool Gowns") and ULTRA Surgical Gowns (hereafter, the "Ultra Gowns") failed industry standard tests, did not pass the relevant standards for gowns represented to be AAMI Level 3 and 4, and are unsafe as a result. And yet from at least as early as 2012 to the present, Defendants have continued to falsely advertise and represent the MicroCool Gowns as AAMI Level 4 and the Ultra Gowns as AAMI Level 3, and misrepresent to customers and the general public that

these gowns provide the highest levels of liquid protection and are thus supposedly effective when treating patients with serious diseases; despite all the while knowing and failing to disclose that they are unsafe for AAMI Level 3 and 4 medical procedures and pose great risk of bodily harm and possibly death to patients and healthcare professionals worldwide.

II. PARTIES

2. Plaintiff Medline Industries, Inc. ("Medline") is an Illinois corporation with its principal place of business in the State of Illinois.

3. Kimberly-Clark is a Delaware corporation with its principal executive offices located in Dallas, Texas. Kimberly-Clark describes itself as a global company focusing on leading the world in essentials for a better life through product innovation and building its personal care, consumer tissue, K-C Professional, and healthcare brands. Kimberly-Clark is principally engaged in the manufacturing and marketing of a wide range of products mostly made from natural or synthetic fibers using advanced technologies in fibers, nonwovens, and absorbency. Kimberly-Clark owns several well-recognized consumer brands in the field of personal care and tissues, including, among others, Huggies, Pull-Ups, Kotex, Depend, Kleenex, Scott, Cottonelle, Viva, and other brand names.

4. Among its business segments, Kimberly-Clark previously operated a healthcare segment, which it described as providing "essentials that help restore patients to better health and improve the quality of patients' lives." In 2013, Kimberly-Clark reported net sales of over $1.6 billion from its healthcare segment alone. This segment was focused on the sale of surgical and infection prevention products for the operating room and other medical supplies, and medical devices focused on pain management, respiratory, and digestive health. Kimberly-Clark described itself as "a global leader in education to prevent healthcare-associated infections." Kimberly-Clark's healthcare products were sold under the "Kimberly-Clark" and "ON-Q" brand names. Its healthcare products included medical exam gloves, facial masks and respirators, and surgical drapes and gowns. According to its 2013 Annual Report, Kimberly-Clark sold its products to, among other entities, "healthcare establishments and high volume public facilities." On information and belief, during all relevant times, Kimberly-Clark's market share of the surgical gown market at issue in this lawsuit exceeded 50%.

5. Defendant Halyard is a Delaware corporation with its principal executive offices located in Alpharetta, Georgia. Halyard describes itself as a global company which seeks to advance health and healthcare by preventing infection, eliminating pain, and speeding recovery. Halyard sells its products in more than 100

countries. It claims that it markets and supports the efficacy, safety, and economic benefit of its products with a significant body of clinical evidence. Halyard has two business segments: Surgical and Infection Prevention, and Medical Devices.

6. Halyard is a publicly traded spin-off company of the healthcare division of Kimberly-Clark previously known as Kimberly-Clark Health Care. The spin-off was completed on or about October 31, 2014. Since that date, Halyard, as opposed to Kimberly-Clark, has sold the MicroCool Gowns and the Ultra Gowns. Halyard was incorporated in February 2014 in anticipation of the spin-off and Kimberly-Clark transferred its healthcare business to Halyard, including the transfer of employees with knowledge relevant to the allegations and conduct described herein, prior to the spin-off. Therefore, the knowledge of Kimberly-Clark Health Care and its employees, executives, executive officers, and others alleged in this Complaint is imputed to Halyard and its employees, executives, executive officers, and others, and Halyard is thus liable for the acts and omissions alleged in this Complaint occurring prior to the spin-off. Halyard is also liable for the acts and omissions as alleged in this Complaint occurring after the completion of the spin-off.

7. The true names and capacities of defendants DOES 1 through 100, inclusive, whether individual, plural, corporate, partnership, associate or otherwise, are not known to Plaintiff, who therefore sues said defendants by such fictitious

names. Plaintiff is informed and believes and thereon alleges that each of the defendants designated herein as DOE are in some manner responsible for the acts and occurrences set forth herein. Plaintiff will seek leave of court to amend this Complaint to show the true names and capacities of defendants DOES 1 through 100, inclusive, as well as the manner in which each DOE defendant is responsible, when the same have been ascertained.

8. Plaintiff is informed and believes, and upon such basis alleges, that at all times herein mentioned, each of the Defendants herein was an agent, servant, employee, co-conspirator, partner, joint venturer, wholly owned and controlled subsidiary and/or alter ego of each of the remaining Defendants, and was at all times acting within the course and scope of said agency, service, employment, conspiracy, partnership and/or joint venture.

9. Defendants, and each of them, aided and abetted, encouraged and rendered substantial assistance in accomplishing the wrongful conduct and their wrongful goals and other wrongdoing complained of herein. In taking action, as particularized herein, to aid and abet and substantially assist the commission of these wrongful acts and other wrongdoings complained of, each of the Defendants acted with an awareness of its primary wrongdoing and realized that its conduct would

substantially assist the accomplishment of the wrongful conduct, wrongful goals, and wrongdoing.

III. JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question), 15 U.S.C. § 1121 (Lanham Act claims) and 28 U.S.C. § 1367 (supplemental jurisdiction).

11. Venue is proper pursuant to 28 U.S.C. § 1391(b) and (c) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district, and because Defendants are subject to the Court's personal jurisdiction in this judicial district.

IV. GENERAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

12. As noted above, this action is brought against Defendants for falsely advertising and promoting medical/surgical gowns as passing AAMI Level 3 and 4 standards, passing industry standard tests relating to liquid protection, and providing the highest levels of protection from the transfer of bodily fluids, bacteria, and infection between patient and healthcare professional. In reality, Defendants have

known since at least as early as 2012 that these gowns failed industry tests, do not satisfy relevant standards, and thus are unsafe.

A. The MicroCool Gowns.

1. The Importance of Liquid Barrier Protections and AAMI Ratings with Regards to Surgical Gowns and Their Importance to Defendants' False Advertisements.

13. Surgical gowns are "medical devices" subject to FDA regulation. Because these medical devices are used by surgeons, nurses and technicians in fluid intensive procedures – i.e., procedures that possibly expose the surgeon, nurse or technician to significant amounts of blood and pathogens – the most important aspect of these medical devices is liquid barrier protection. Defendants, through their own internal documents, acknowledge that "barrier protection" is a "key characteristic" for "gown selection" and describe such protections as the "most important selection criteria."

14. The industry standard for measuring the level of liquid barrier protection a gown provides is the Association for the Advancement of Medical Instrumentation standard otherwise known as "AAMI." Since 2004, the FDA has recognized the PB70 standard published by the American National Standards

Institute ("ANSI")/AAMI and set forth in a document titled "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities" as being sufficient to pass the FDA's 510(k) clearance process.

15. The AAMI PB70 standard creates a four-level hierarchy of surgical protection that is meant to provide medical professionals an intuitive and integrated approach to selecting the appropriate type of protective apparel for a given situation. AAMI performance levels range from 1 (least protective) to 4 (most protective). AAMI Level 1 is to be used in "MINIMAL risk situations" providing only a "slight barrier" to fluid penetration with a single test of "water impacting the surface of the gown material" being conducted. Levels 2 and 3 are to be used in "LOW" and "MODERATE" risk situations and also involve distinct tests to determine fluid penetration and barrier protection. Level 4 is to be used in "HIGH risk situations" and thus must prevent "all fluid penetration for up to 1 hour" with barrier performance "tested with a simulated blood containing a virus."

16. AAMI guidelines are a widely accepted system of classification for protective apparel and drapes based on liquid barrier performance. Thus, protective apparel for medical professionals, also commonly referred to as "personal protective equipment" or "PPE" (including surgical gowns), are labeled based on their minimum AAMI level so that medical professionals can easily select the appropriate

gown depending on the type of surgery or procedure that they are performing. The more fluid intensive and risky the situation, the higher the AAMI level of protection they should select.

17. For a surgical gown to qualify as AAMI Level 4, it must pass the ASTM 1671 test in the "critical zones." The "critical zones" refer to the areas on the front of the gown that are most likely to be exposed to fluids. The "critical zones" are the sleeve seams and the front body. The ASTM 1671 test is conducted by placing a solution of simulated blood and virus particles on the outside of the gown and pressurized at specified tolerances for specified time periods to see if the blood or virus material passes through the surgical gown. If no simulated blood or virus material passes through the gown, then it is a pass for that sample.

18. The other three levels of performance established in AAMI PB70 involves different tests for measuring the liquid barrier performance of surgical gown materials. For instance, a hydrostatic test is used to set performance requirements for Level 2 and 3 surgical gowns. Hydrostatic testing is based on a standardized method established by the American Association of Textile Chemists and Colorists (AATCC). This test method is AATCC 127, *Water resistance: Hydrostatic pressure test,* which involves measuring the applied pressure that results in water penetration through a material or seam specimen that is reported in

centimeters of water column pressure. The hydrostatic test does not involve any microbial surrogate and solely uses water as the challenge liquid. A physical measurement of pressure (in centimeters) is provided as the test result.

19. An impact penetration test is also used to set performance requirements for Level 1, 2, and 3 surgical gowns. Impact penetration testing is also based on an AATCC standard method. For this testing, AATCC 42, *Water resistance: Impact penetration test,* is used. The test method involves the placement of the uniformly cut material or seam specimen on an inclined clipboard and the release of 500 milliliters of water into a funnel to which is attached a specified nozzle. Water sprays from the nozzle onto the inclined specimen. Underneath the specimen is a piece of specialized blotter paper that is weighed before and after the test to determine the amount of water that penetrates through the sample as a result of the water exposure. Test results are provided as the mass of water in grams that is found to penetrate the specimen.

20. If the gowns fail to consistently pass the relevant tests, it is not permissible to label any of the gowns as passing AAMI Level 3 or 4 standards.

2. Defendants Marketed the Gowns as Passing AAMI Level 3 and 4 Standards.

21. From approximately 2011 to the present and continuing, Defendants have promoted, marketed, advertised, and offered for sale to consumers, patients, doctors, clinics, and healthcare facilities worldwide surgical gowns sold under the name "MICROCOOL* Breathable High Performance Surgical Gowns" (hereafter, the "MicroCool Gowns"). Kimberly-Clark began manufacturing and selling the MicroCool Gowns in or around August 2011. Defendants uniformly claimed to their prospective customers that the MicroCool Gowns provide the highest level of liquid barrier protection available. The packaging of the MicroCool Gowns prominently featured the "AAMI Level 4" claim at the top of the package on all gowns. Defendants also represented on all packaging that "MicroCool Surgical Gowns pass ASTM F 1671, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration of Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System." Further, the gowns themselves are marked as AAMI Level 4 gowns. Attached as Exhibit 1 and incorporated herein by this reference is a true and correct copy of an example of the actual package containing one of the MicroCool Gowns.

22. In addition to the labeling of the gowns, the "AAMI Level 4" claim was central to Defendants' advertising, marketing, and promotion of the MicroCool Gowns. For example, in a press release introducing the MicroCool Gowns, Kimberly-Clark stated they passed the AAMI Level 4 Standard for liquid barrier protection and represented that the "gown helps prevent blood and other bodily fluids from penetrating through to the clinician's skin during any procedure and is specifically designed for the most demanding and fluid-intensive procedures." Kimberly-Clark's Vice President of Global Sales and Marketing, Mr. John Amat, was quoted as saying "[t]he gown delivers surgeons and surgical staff a full spectrum of protection and the assurance of barrier integrity, allowing them to concentrate solely on patient care during long and stressful procedures and not on their risk of exposure." Attached hereto as Exhibit 2 and incorporated herein by this reference is a true and correct copy of the press release dated May 16, 2011.

23. Therefore, by claiming the MicroCool Gowns are AAMI Level 4 gowns, Defendants represent that they provide "the highest barrier protection rating available for gowns." Defendants further represent that the MicroCool Gowns provide "Level 4" liquid barrier protection to "critical zones." These "critical zones," according to Defendants, include the front area of the gown from chest to knees and "the sleeves from the cuff to above the elbow." Attached as Exhibit 3 and

incorporated herein by this reference is a true and correct copy of Kimberly-Clark's full description of the MicroCool Gowns, available on its website as of October 29, 2014.

24. In addition, from approximately 2011 to the present and continuing, Defendants have promoted, marketed, advertised, and offered for sale to consumers, patients, doctors, clinics, and healthcare facilities worldwide surgical gowns sold under the name ULTRA Surgical Gown (hereafter, the "Ultra Gowns"). Defendants claimed to their prospective customers that the Ultra Gowns are intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. Further, Defendants claimed to their prospective customers that the Ultra Gowns fully satisfy the AAMI Level 3 requirements for liquid barrier performance. The packaging of the Ultra Gowns prominently featured the "AAMI Level 3" claim at the top of the package on all gowns. Further, the gowns themselves are marked as AAMI Level 3 gowns. Attached hereto as Exhibit 4 and incorporated herein by this reference is a true and correct copy of an example of the actual package containing one of the Ultra Gowns.

25. Defendants also represented that the Ultra Gowns provide Level 3 liquid barrier protection in the "critical zones," which include the front area of the gown from the chest to the knees, and the sleeves from the cuff to above the elbow.

Further, Defendants represented that the Ultra Gowns provide fluid resistance barrier protection to prevent blood strikethrough and fluid contamination.

26. In the months following the introduction of the MicroCool Gowns and Ultra Gowns in the marketplace, Kimberly-Clark continued to aggressively market the gowns as passing the standards for the highest level of barrier protection, and being safe and superior to rival gowns, including those sold by Medline.

3. Defendants Knew their Gowns Did Not Pass the Standards They Were Represented to Satisfy, but Claimed Otherwise and Failed to Disclose the Truth.

27. Defendants' representations concerning the level of protection of the MicroCool Gowns and Ultra Gowns are not true, and Defendants have known they are not true since at least February 2012. Despite this knowledge, Defendants have not corrected their representations (including in its advertising, marketing, and labeling of the product), have not stopped selling the MicroCool and Ultra Gowns, have not recalled the MicroCool and Ultra Gowns they have already sold and/or caused to be placed in the distribution channel, have not reported the truth to the FDA, and have not alerted their customers that have purchased these gowns that the gowns were not and are not as represented. Further, despite this knowledge, Defendants continued to advertise and promote their gowns using false

representations and material omissions concerning the level of protection of the MicroCool Gowns and the Ultra Gowns in order to improperly divert sales of gowns away from Defendants' competitors, including Medline.

28. In fact, not only do the MicroCool Gowns and Ultra Gowns not *satisfy* the relevant standards for liquid barrier protection, Kimberly-Clark has known since at least 2012 that their gowns have *failed* the relevant tests, do not pass the relevant AAMI standard, and thus, pose a serious risk of causing physicians, healthcare professionals and patients to be unknowingly exposed to serious bacteria, viruses and illness, including but not limited to Ebola.

29. On February 29, 2012, Kimberly-Clark received failing ASTM 1671 tests results from an independent testing lab, Intertek. These results created a problem for Kimberly-Clark because, as set forth above, it had already falsely marketed the MicroCool Gowns as providing the highest level of barrier protection and passing the AAMI Level 4 standard. Upon learning of this failure, instead of conducting a genuine investigation to search for the root cause of the sleeve seam failures, Kimberly-Clark sought to find a pretext to retest the gowns to make sure they "pass like the other two lots." According to the Kimberly-Clark engineer overseeing the testing of the gowns, they simply needed to "try and come up with a

reason/rationale" to justify a retest, noting that it "doesn't have to be a proven reason."

30. In addition to occasionally sending gowns for ASTM 1671 testing to Intertek, Kimberly-Clark also had IPS, another lab, conduct monitoring tests each month on the gowns during the year 2012. This testing, conducted monthly, revealed consistent sleeve seam failures in 2012. Consequently, by mid-2012, Kimberly-Clark concluded that the MicroCool Gowns "failed the testing," did not pass the standards for AAMI Level 4 testing, and therefore could not be represented as AAMI Level 4.

31. In January 2013, Cardinal Health, one of Kimberly-Clark's major distributors, shared test results of the MicroCool Gowns with Kimberly-Clark during litigation between the two companies. Cardinal commissioned the test, which showed that the MicroCool Gowns were failing at an alarming rate. Specifically, the test was performed by Intertek in December 2012 and showed that ASTM F1671 tests of approximately 96 random samples of the MicroCool Gowns from three separate manufacturing lots were conducted, with over 48 of the gowns failing the test and no fewer than 32 of those gowns experiencing catastrophic failures.

32. On February 23, 2013, Kimberly-Clark sent another lot of MicroCool Gowns to Intertek for testing. Of the 85 samples tested, 18—or 21.12%--failed. The

testing that Kimberly-Clark ordered from Intertek confirmed (1) what their internal, monthly 2012 testing had shown, (2) what the previous Intertek failure that KC sought a retest on had shown, (3) what a commissioned test received the preceding month from one of Kimberly-Clark's distributors had shown; and (4) what Kimberly-Clark had already admitted within its own internal documents - that the gowns had strikethrough, did not pass the highest level of liquid barrier protection and were unsafe.

33. In March 2013, Kimberly-Clark again had Intertek test a lot of sleeve seams to see if the gowns could pass the ASTM 1671 test and, in turn, be properly labeled AAMI Level 4. The test results, dated March 31, 2013, show that three out of 79 failed—within acceptable tolerances for AAMI Level 4. However, the reason that only 79 gowns were tested as opposed to the 85 that had been sent is because when Intertek opened up the packages to test the gowns, the sleeves on six of the gowns were visibly open and not sealed. As an email from Intertek to Kimberly-Clark explains, six of the "samples were found to have seal problem" and Intertek would not charge them "for these 6 untested samples." Kimberly-Clark's internal tracking of test results also noted this, and concluded the test to be a failure.

34. In or around March and April 2013, Kimberly-Clark negotiated a settlement in its three years of litigation with Cardinal Health. Significantly, in its

in-house counsel's communications with Cardinal Health's lawyer, Kimberly-Clark acknowledged that Kimberly-Clark had a "known quality issue, and it may continue during the subsequent 12 month period." In addition, as part of the settlement, Kimberly-Clark's in-house counsel agreed to indemnify Cardinal Health "for any liability arising from any current AAMI IV product nonconformance"—an admission that the MicroCool Gowns were "non-conforming" product. Further, in connection with the agreement, Kimberly-Clark sought to keep the nonconformance a secret from other competitors, including Plaintiff.

35. Similarly, beginning in or around March 2012, Kimberly-Clark also became aware of AAMI Level 3 testing failures relating to the Ultra Gowns. The problem with the Ultra Gowns related not only to the sleeves, but also to the fabric used to produce the gowns and the gowns' ties. These test results showed that the Ultra Gowns did not consistently pass AAMI Level 3 requirements and thus could not be represented as such.

36. As a result of these failed test results, Defendants knew that they could no longer honestly represent the MicroCool Gowns as being "impermeable," of passing AAMI Level 4, of passing ASTM F1670 and F1671 testing standards, and/or of satisfying ANSI/AAMI PB70. They also knew they could not represent the Ultra Gowns as satisfying AAMI Level 3, or of passing hydrostatic pressure testing

standards. Further, Defendants knew they should take immediate action to announce that the MicroCool and Ultra Gowns did not pass appropriate standards; recall the gowns; alert Federal, State and local governments and the FDA; alert physicians, healthcare professionals and patients worldwide; and undertake efforts to immediately cause the gowns to be removed from the shelves and distribution channels of healthcare facilities and distributors worldwide. In short, Defendants knew that their gowns were not safe for the intended uses and placed both patients *and* healthcare professionals at risk of serious infection and bodily harm.

37. However, instead of taking appropriate and immediate action to protect healthcare professionals and the public at large, Defendants took extensive measures to keep information regarding the inability of their gowns to pass industry standards concealed from purchasers and healthcare professionals. Defendants did not disclose the truth to purchasers and others regarding the gowns; did not stop making its false representations to customers and others regarding the gowns, did not recall the gowns; did not alert Federal, State and local governments and the FDA; did not alert physicians, healthcare professionals and patients worldwide; and did not undertake efforts to immediately cause the gowns to be removed from the shelves and distribution channels of healthcare facilities and distributors worldwide.

38. The testing failures of the MicroCool Gowns and Ultra Gowns were also confirmed by Keith Edgett, Kimberly-Clark's Global Director of Surgical and Infection Prevention. According to Edgett, during his tenure at the company between March 2011 and October 2013, Kimberly-Clark was well aware that the MicroCool Gowns, along with the Ultra Gowns, were not compliant. The failures were so common that Edgett suggested that no more AAMI testing be performed and that a scientist who reported to him travel to Honduras (where the gowns were manufactured) in an attempt to try and figure out why the failures were occurring. Kimberly-Clark's quality division, likewise, recognized the MicroCool Gowns "failed" AAMI Level 4 testing and therefore could not be represented as being AAMI Level 4. Ms. Joanne Bauer, the then President of Kimberly-Clark's Healthcare division, subsequently convened a meeting about AAMI non-compliance. Edgett described the meeting as follows:

> The – what I would categorize as the – most significant experience for me occurred in late 2012, early 2013, where we were in a meeting with Joanne, all of her direct reports were in the room, there were a number of others that would be my colleagues that held director titles. I'd say there were somewhere between 18 and 25 people in the boardroom.
>
> And at one point in the discussion Joanne looked at me, and she was emotional, and stated that she was sick and tired of all the noncompliance issues that had – had – she

> had – that she had experienced **for more than a decade**, and she wanted me to fix it.

39. Kimberly-Clark thus formed a "Fast Solution Team" in which Edgett was "asked to lead a team to resolve our current AAMI issues" which would report back to Ms. Bauer on a weekly basis. This team later confirmed that the Microcool and Ultra gowns were noncompliant and the fact had been well known within Kimberly-Clark.

40. Kimberly-Clark subsequently initiated a "Corrective and Preventative Action" of "CAPA" to resolve the known problems with the gowns. Importantly, when this CAPA was opened in February 2013, Kimberly-Clark admitted in its internal documents that the "problem" was that the gowns **"are not meeting the AAMI Standard requirement as required in ASTM 1670 and the 510(k)"** and was caused because **"[c]urrent Band [sic] Sealing technology of gown sleeves is inadequate to meet the AAMI requirement for barrier performance."** This CAPA remained opened, i.e. unresolved, for at least another 18 months.

41. By the end of 2013, Kimberly-Clark's quality department acknowledged that the bar "sealing technology of gown sleeves is inadequate to meet the AAMI requirement for barrier performance."

42. Kimberly-Clark's testing failures were also consistent with the feedback that Kimberly-Clark was getting from the field. Sales representatives were

receiving complaints about the gowns, particularly strikethrough and leaking in the sleeve area. One Kimberly-Clark sales representative wrote on August 22, 2012 that "[s]urgeons don't feel like these issues are all channelling or roll down" and states that he "would highly encourage you to re-examine the sleeves," asking "[i]s there is any way to make them stronger" because "[t]hey do pull apart pretty easily."

4. Defendants Attempted to Use the Ebola Crisis to Its Benefit and Promote the Sale of Its Noncompliant Gowns.

43. Despite its knowledge as to its prior false representations and concealment, in public statements, Kimberly-Clark sought to disadvantage its competitors in the marketplace and represented that the MicroCool Gowns are *safe to use in connection with patients suspected of contracting the Ebola virus*. Kimberly-Clark's website stated as follows:

> As concerns around the spread of the Ebola virus continue to grow, the number of inquiries we receive regarding recommendations for PPE [i.e., "Personal Protective Equipment"] and our plans for Pandemic Preparedness are growing in tandem. Therefore, we want to proactively provide you with guidance on preparing for a pandemic **as well as solutions for proper PPE**. We are providing you with a clinical Kimberly-Clark Ebola Virus Precautions Brief and a Kimberly-Clark Personal Protection Solutions guide as well as other resources to answer questions you have about the Ebola Virus Disease.

44. Below this statement on its website, Kimberly-Clark shared a link inviting visitors to download the "Kimberly-Clark Personal Protection Solutions Guide," which advised healthcare facilities to use the MicroCool Gowns in connection with treating patients who may be infected with the Ebola virus. The link to this list of Kimberly-Clark products, which included the MicroCool Gowns, was also available on Kimberly-Clark's letter to customers entitled the "Kimberly-Clark Pandemic Preparedness Customer Letter" dated August 14, 2014. Attached hereto as Exhibit 5 and incorporated herein by this reference is a true and correct copy of a page relating to Ebola preparedness available on Kimberly-Clark's website. Attached hereto as Exhibit 6 is a true and correct copy of Kimberly-Clark's August 14, 2014 letter posted on its website. Attached hereto as Exhibit 7 and incorporated herein by this reference is a true and correct copy of the list of Kimberly-Clark "Personal Protective Equipment" products, which include the MicroCool Gowns and which Kimberly-Clark recommended in connection with the treatment of suspected or confirmed Ebola patients.

45. Further, on September 19, 2014, Kimberly-Clark issued a document entitled "Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief." In this document, Kimberly-Clark provided a list of recommendations for "Personal Protection" from the Ebola virus, as well as the use of "appropriate personal

protective equipment (PPE)." With respect to surgical gowns, Kimberly-Clark advised healthcare professionals to use "Level 4" gowns—the represented clearance level for the MicroCool Gowns—for working with Ebola patients. Attached hereto as Exhibit 8 and incorporated herein by this reference is a true and correct copy of this document.

46. On October 10, 2014, AAMI issued a press release entitled "Surgery Protocol for Ebola Includes AAMI Gown Standard." In the press release, AAMI recommended that surgeons and healthcare professionals wear "AAMI Level 4" surgical gowns and drapes when operating on suspected or confirmed Ebola patients. On October 21, 2014, the American College of Surgeons issued a statement echoing the AAMI guidance by advising that due to the significant risk of exposure to blood or bodily fluids, all operating room personnel should wear "AAMI Level 4" impervious surgical gowns. Again, while customers, the public and the healthcare community was being led to believe that "AAMI Level 4" gowns manufactured and distributed by Defendants were safe for Ebola patients or other sensitive operations, and Defendants' gowns had satisfied critical industry standards and were "impermeable," Defendants together with certain of its employees, executives, and agents knew this to be untrue.

47. The MicroCool Gowns and Ultra Gowns remained noncompliant until at least 2015 while Defendants attempted to fix the problem with the sleeve seams. Knowing that the manufacturing process was flawed and creating noncompliant gowns, Kimberly-Clark unsuccessfully sought to fix the sleeve seaming problem by replacing the bar sealers with Bosch band sealers.

B. Plaintiffs Sold Competing Gowns and Suffered Harm from Defendants' False Advertising and Unfair Competition.

48. Medline is the largest privately held manufacturer and distributor of medical supplies. Medline's products include surgical gowns that compete with the MicroCool Gowns and Ultra Gowns. Medline sells its gowns throughout the United States, including in California and in this judicial district.

49. As shown above, purchasers of the MicroCool Gowns and Ultra Gowns were likely to be, and were, misled and deceived by Defendants' product labeling, marketing, and advertising. Defendants' false and misleading product labeling, marketing, and advertising is damaging to the reputation and goodwill of Medline and is damaging to the purchasers and users of Defendants' products. These false and misleading representations, including fraudulent omissions, were designed to induce customers, including hospitals, surgery centers, and clinics, to purchase

Defendants' gowns over Medline's gowns. Specifically, Defendants' false and misleading representations and concealment of material facts deceived purchasers into believing that Defendants' gowns performed as well, or better than, Medline's gowns. In this way, Defendants enticed purchasers who would otherwise buy Medline's gowns to buy Defendants' gowns instead. In doing so, Defendants wrongfully misled and deceived customers, and tricked them into believing that they were getting a similar or superior product for the same price or a lower price, when in fact they were getting a very different product that did not perform to the claimed standards.

50. For example, on December 1, 2012, Kimberly-Clark internally disseminated a "MICROCOOL* Update" specifically attempting to contrast the MicroCool Gowns from the gowns sold by Medline, its competitor, with the claim that "Medline Prevention Plus is NOT AAMI 4!!!!" and touting the success of an account consultant, Michael Jacoby, in selling MicroCool Gowns over the competition claiming that the Medline gown was "having strikethrough problems."

51. The natural, probable, and foreseeable result of Defendants' wrongful conduct has been to cause confusion, deception, and mistake in the surgical gown market as a whole, to deprive Medline of business and goodwill, and to injure Medline's relationships with existing and prospective customers.

52. Medline is informed and believes and thereupon alleges that Defendants' wrongful conduct has resulted in increased sales of Defendants' MicroCool Gowns and Ultra Gowns, while hindering sales of Medline's gowns and other products and damaging Medline's goodwill. Medline has sustained and will sustain damages as a result of Defendants' wrongful conduct.

53. Defendants' wrongful conduct has deceived, and caused confusion to, customers in the Central District of California (the "Central District"), and further, Defendants' passing off has occurred in the Central District because deceived customers purchased Defendants' MicroCool Gowns and Ultra Gowns in substantial amounts in the Central District. More specifically, Defendants advertised, promoted, marketed, and sold the MicroCool Gowns and Ultra Gowns in the Central District. For instance, during the relevant time period, Defendants sold over $19.1 million of the MicroCool Gowns in California, of which, more than $16.7 million were to purchasers in this judicial district. These sales to purchasers in the Central District constituted roughly almost 15 percent of Defendants' total sales of the MicroCool Gowns in the United States. In addition, during the relevant time period, Defendants made sales of the Ultra Gowns to purchasers in California well in excess of $7 million and these sales constituted a percentage of their total sales in the United States that is roughly in the same proportion as their California sales of MicroCool

Gowns. During the relevant time period, Defendants sold in excess of $4.5 million of the Ultra Gowns to purchasers in the Central District. Therefore, a substantial amount of sales in violation of the law occurred in the Central District.

V. CLAIMS FOR RELIEF

COUNT ONE

False Advertising and Promotion Under Lanham Act

Section 43(a) (15 U.S.C. § 1125(a))

(Against All Defendants)

54. Defendants have made and distributed, in interstate commerce and in this judicial district, false or misleading statements and/or statements that omit material facts regarding their products in commercial advertising and promotion. [*See* ¶¶21, 24, 48-49, 53, *supra*.] This advertising and promotion contains actual misstatements and/or misleading statements and fails to disclose material facts regarding the nature, characteristics, and/or qualities of Defendants' products, as alleged in this Complaint, including, but not limited to, in paragraphs 12, 21 through 43, 47, and 49, *supra* (which are restated and re-alleged herein by this reference).

Defendants' false and misleading descriptions and representations of fact, and concealment and omissions of fact, include, but are not limited to, the following:

(a) Falsely representing that the MicroCool Gowns passed AAMI Level 4 standards for liquid barrier protection.

(b) Falsely representing that the MicroCool Gowns passed ASTM F1670 and ASTM F1671 standards for resistance of materials used in protective clothing.

(c) Falsely representing that the MicroCool Gowns passed ASTM F1671 standards for bacteriophage penetration.

(d) Falsely representing that the MicroCool Gowns provided "Level 4" liquid barrier protection to "critical zones," which include the front of the gown from chest to knees and the sleeves from the cuff to above the elbow.

(e) Falsely representing that the Ultra Gowns passed AAMI Level 3 standards for liquid barrier protection.

(f) Falsely representing that the Ultra Gowns provided "Level 3" liquid barrier protection to "critical zones," which include the front of the gown from chest to knees and the sleeves from the cuff to above the elbow.

(g) Falsely representing that the MicroCool and Ultra Gowns will not leak bodily fluids or pass bacterial organisms either from the healthcare worker to the patient, or vice versa, and are safe for use in the treatment of patients with infectious diseases or whose treatment require a sterile environment.

(h) Falsely representing the foregoing to customers regarding the MicroCool and Ultra Gowns and thereby representing that their gowns are superior to medical gowns sold by Medline.

(i) Failing to disclose that at times throughout the period beginning in 2012 through at least 2015, Kimberly-Clark and/or Halyard was aware that the MicroCool Gowns and Ultra Gowns had failed industry standard tests relating to liquid barrier protection and thus were not passing the AAMI Standard requirement for barrier performance.

(j) Failing to disclose that Kimberly-Clark and/or Halyard had reason to believe, based on failed industry standard tests during the period from 2012 through early 2015, that the gowns did not provide liquid barrier protection to critical zones of the gowns, which included the sleeves from the cuff to above the elbow.

(k) Failing to disclose that use of the MicroCool Gowns and/or Ultra Gowns during liquid intense surgical procedures posed a safety risk to the doctors and nurses involved in the procedures.

(l) Failing to disclose the foregoing to customers regarding the MicroCool and Ultra Gowns in an effort to induce customers to believe that their gowns are superior to medical gowns sold by Medline.

55. These false and misleading statements and failures to disclose material facts actually deceive, or have a tendency to deceive, a substantial segment of Medline's customers and potential customers. Additional facts supporting this deception are described in this Complaint, including but not limited to, in paragraphs 21 through 43, 47, and 49, *supra* (which are restated and re-alleged herein by this reference).

56. This deception is material in that it is likely to influence, and/or had a material effect on, the purchasing decisions of Medline's customers. Additional facts supporting materiality are set forth in this Complaint, including but not limited to, in paragraphs 13 through 18, 21 through 26, 38, 42 through 46, and 50, *supra* (which are restated and re-alleged herein by this reference).

57. As a result of Defendants' conduct, Medline has been injured by diversion of sales of its products to Defendants' products, and/or by lessening of the goodwill which its products enjoy with the buying public.

58. Defendants have caused, and will continue to cause, immediate and irreparable injury to Medline, including injury to its business, reputation, and goodwill, for which there is no adequate remedy at law. As such, Medline is entitled to an injunction under 15 U.S.C. § 1116 restraining Defendants, their agents, employees, representatives, and all persons acting in concert with them from engaging in further acts of false advertising and promotion, and ordering removal of all Defendants' false advertisements and promotions.

59. Pursuant to 15 U.S.C. § 1117, Medline is entitled to recover from Defendants the damages sustained by Medline as a result of Defendants' acts and omissions in violation of section 43(a) of the Lanham Act. Medline is at present unable to ascertain the full extent of the monetary damages it has suffered by reason of Defendants' acts and omissions, but such amount is believed to be well in excess of $1,000,000.

60. Pursuant to 15 U.S.C. § 1117, Medline is further entitled to recover from Defendants the gains, profits, and advantages that they have obtained as a result of their acts and omissions. Medline is at present unable to ascertain the full amount

of the gains, profits, and advantages Defendants have obtained by reason of their acts and omissions, but such amount is believed to be well in excess of $1,000,000.

61. Pursuant to 15 U.S.C. § 1117, Medline is further entitled to recover the costs of this action. Moreover, Medline is informed and believes, and thereupon alleges, that Defendants' conduct was undertaken willfully and with the intention of causing confusion, mistake, or deception, making this an exceptional case entitling Medline to recover additional damages and reasonable attorneys' fees.

62. Additional details concerning Medline's injuries as a result of Defendants' false and misleading statements and/or omissions and failures to disclose material facts are set forth in this Complaint, including but not limited to, in paragraphs 49 through 52, *supra* (which are restated and re-alleged herein by this reference).

63. As noted above (see paragraph 6), Defendant Halyard is a spin-off company of the healthcare division of Defendant Kimberly-Clark previously known as Kimberly-Clark Health Care. The spin-off was completed on or about October 31, 2014. Accordingly, Kimberly-Clark, which manufactured, marketed, and sold the MicroCool Gowns and Ultra Gowns before the spin-off, is liable for the acts and omissions alleged in the Complaint occurring before the spin-off. Further, because Kimberly-Clark's acts and omissions before the spin-off, including but not limited

to, its failure to manufacture compliant AAMI Level 4 MicroCool Gowns and AAMI Level 3 Ultra Gowns, continued to impact, and cause injury, to Medline even after the spin-off, Defendant Kimberly-Clark is also liable for the acts and omissions alleged in the Complaint occurring after the spin-off.

64. In addition, for the reasons set forth above in paragraph 6, Halyard is liable for the acts and omissions alleged in this Complaint both before and after the spin-off.

COUNT TWO

Common Law Unfair Competition

(Against All Defendants)

65. Defendants' false and misleading statements and omissions of material fact concerning the MicroCool Gowns and Ultra Gowns, along with the other wrongful conduct alleged above, constitute unfair competition in violation of the common law. These false and misleading statements and omissions of material fact were intended to induce customers to purchase Defendants' MicroCool Gowns and Ultra Gowns instead of the gowns sold by Medline.

66. Defendants, in connection with the marketing of their MicroCool Gowns and Ultra Gowns, made representations relating to these products, and

omitted and concealed facts relating to these products, which were likely to deceive or mislead prospective purchasers, additional details of which are described in this Complaint, including but not limited to, in paragraphs 12, 21 through 43, 47, 49, and 54, *supra* (which are restated and re-alleged herein by this reference).

67. Defendants' representations, and omissions and concealed facts, relating to the MicroCool Gowns and Ultra Gowns, which likely deceived or misled prospective purchasers, resulted in the commercial detriment of Medline. Defendants' representations, and omissions and concealed facts, were material in that they were likely to affect the conduct of prospective purchasers. Additional facts supporting materiality are set forth in this Complaint, including but not limited to, in paragraphs 13 through 18, 21 through 26, 38, 42 through 46, and 50, *supra* (which are restated and re-alleged herein by this reference).

68. There is a reasonable basis for believing that Defendants' representations, and omissions and concealed facts, have caused, or are likely to cause, a diversion of trade from Medline or harm to Medline's reputation or goodwill. Additional details concerning Medline's injuries as a result of Defendants' wrongdoing are set forth in this Complaint, including but not limited to, in paragraphs 49 through 52, *supra* (which are restated and re-alleged herein by

this reference). As a direct and proximate result of Defendants' wrongdoing, Medline has suffered damages in an amount to be proven at trial.

69. As noted above (see paragraph 6), Defendant Halyard is a spin-off company of the healthcare division of Defendant Kimberly-Clark previously known as Kimberly-Clark Health Care. The spin-off was completed on or about October 31, 2014. Accordingly, Kimberly-Clark, which manufactured, marketed, and sold the MicroCool Gowns and Ultra Gowns before the spin-off, is liable for the acts and omissions alleged in the Complaint occurring before the spin-off. Further, because Kimberly-Clark's acts and omissions before the spin-off, including but not limited to, its failure to manufacture compliant AAMI Level 4 MicroCool Gowns and AAMI Level 3 Ultra Gowns, continued to impact, and cause injury, to Medline even after the spin-off, Defendant Kimberly-Clark is also liable for the acts and omissions alleged in the Complaint occurring after the spin-off.

70. In addition, for the reasons set forth above in paragraph 6, Halyard is liable for the acts and omissions alleged in this Complaint both before and after the spin-off.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows:

ON THE FIRST CAUSE OF ACTION FOR FALSE ADVERTISING UNDER SECTION 43(a) OF THE LANHAM ACT

1. For damages in a sum to be proven at trial, including but not limited to, the gains, profits, and advantages Defendants have obtained as a result of their acts and omissions, and injury to Medline's business, reputation, and goodwill.

2. For additional damages above the amount found as actual damages and/or above the amount of Defendants' profits obtained through Defendants' wrongful conduct pursuant to 15 U.S.C. § 1117.

3. For Medline's costs of the action and attorneys' fees to the extent permitted under 15 U.S.C. § 1117, or as otherwise permitted by law.

4. For an injunction precluding the wrongful conduct described herein.

5. For pre and post judgment interest and costs of suit incurred herein.

6. For such other and further relief as the Court may deem just and proper.

ON THE SECOND CAUSE OF ACTION FOR COMMON LAW UNFAIR COMPETITION

1. For compensatory damages in a sum to be proven at trial.

2. For an injunction precluding the wrongful conduct described herein.

3. For pre and post judgment interest and costs of suit incurred herein.

4. For attorneys' fees incurred herein, to the extent permitted by law.

5. For such other and further relief as the Court may deem just and proper.

Dated: March 14, 2018

EAGAN AVENATTI, LLP

By: /s/ Michael J. Avenatti
Michael J. Avenatti

L. LIN WOOD, P.C.

By: /s/ L. Lin Wood
L. Lin Wood
Attorneys for Plaintiff

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: March 14, 2018

EAGAN AVENATTI, LLP

By: /s/ Michael J. Avenatti
Michael J. Avenatti (*pro hac vice*)
Attorneys for Plaintiff

L. LIN WOOD, P.C.

By: /s/ L. Lin Wood
L. Lin Wood
GA Bar No. 774588
Attorneys for Plaintiff

CERTIFICATION UNDER L.R. 7.1D.

Pursuant to Northern District of Georgia Civil Local Rule 7.1D, the undersigned counsel certifies that this SECOND AMENDED COMPLAINT is a computer document and was prepared in Times New Roman 14 point font, as mandated in Local Rule 5.1C.

This 14th day of March, 2018.

/s/ Michael J. Avenatti

CERTIFICATE OF SERVICE

This is to certify that I have this day electronically filed the foregoing SECOND AMENDED COMPLAINT via the CM/ECF system, which will automatically send e-mail notification to the attorneys of record.

This 14th day of March, 2018.

/s/ G. Taylor Wilson